

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

WYETH,)	
)	
)	
Plaintiff,)	
)	Civil Action No.: 06-222 JJF
v.)	
)	
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	
_____)	

**OPPOSITION OF DEFENDANT IMPAX LABORATORIES, INC.
TO PLAINTIFF'S MOTION TO STRIKE
IMPAX'S UNCLEAN HANDS DEFENSE AND
TO DISMISS IMPAX'S UNENFORCEABILITY COUNTERCLAIM**

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I. NATURE AND STAGE OF PROCEEDINGS

This case represents the latest attempt by Plaintiff Wyeth to use the patents-in-suit¹ to block or delay from the market a generic version of its product EFFEXOR® XR, which is a formulation of the anti-depressant medication venlafaxine hydrochloride. Defendant Impax Laboratories, Inc. (“Impax”) informed Wyeth months ago that its generic venlafaxine hydrochloride extended release capsules would not infringe Wyeth’s patents because they would not contain spheroids comprised of microcrystalline cellulose, an ingredient required by each of the claims of the patents-in-suit. Not only does almost every claim of the patents-in-suit *expressly* require microcrystalline cellulose, but in recent litigation brought by Wyeth in the District of New Jersey, that Court properly construed *all* of the asserted claims to require the presence of microcrystalline cellulose, the compound that is absent from the accused products here.

Nonetheless, Wyeth initiated this action against Impax on April 5, 2006 alleging patent infringement under 35 U.S.C. § 271(e)(2)(A) by reason of Impax’s submission to the Food and Drug Administration (“FDA”) of Abbreviated New Drug Application (“ANDA”) No. 78-057. D.I. 1. Impax filed its Answer and Counterclaims on April 25, 2006, denying infringement and raising the defense and counterclaim that the patents-in-suit are unenforceable due to Wyeth’s unclean hands in asserting patents it knows are not infringed. D.I. 7.

On May 12, 2006, Wyeth served the instant motion to strike Impax’s unclean hands defense and to dismiss Impax’s unenforceability counterclaim

¹ The patents-in-suit are U.S. Patent No. 6,274,171 (“171 patent”), U.S. Patent No. 6,403,120 (“120 patent”), and U.S. Patent No. 6,419,958 (“958 patent”).

under the theory that they are insufficiently pled. D.I. 9. We show herein that this motion could only have been asserted for the purpose of delay and to make this litigation as expensive as possible. At this stage in the proceedings when no discovery has been taken, this matter is hardly worthy of a motion. As Judge Robinson stated as to a previous case in which a plaintiff attempted to strike an unclean hands defense:

In complex litigation, such as cases involving patent infringement, it is through the discovery process that the parties refine and focus their claims. At this stage in the litigation, the court declines to strike defendant's affirmative defenses [of unclean hands] until adequate discovery has been completed.²

Impax submits this memorandum in opposition to Plaintiff Wyeth's motion to strike Impax's unclean hands defense and to dismiss Impax's unenforceability counterclaim.

II. SUMMARY OF ARGUMENT

Impax pled its unclean hands defense and unenforceability counterclaim with sufficient particularity under FRCP 8 by disclosing all of the facts forming the basis for that defense and counterclaim.

In summary, Wyeth is attempting to enforce the patents-in-suit against Impax even though Wyeth knows that Impax's generic product does not contain all of the claimed elements of the patents-in-suit. When Impax informed Wyeth that it had filed an ANDA to sell a generic version of EFFEXOR® XR, Impax also informed Wyeth that its product would not infringe the patents-in-suit, in part because its product would not contain spheroids comprised of microcrystalline cellulose. *See Declaration of Mary B. Matterer in Support of Impax's Opposition*

² *McKesson Info. Solutions, LLC v. The Trizetto Group*, 2005 WL 914776, *2 (D. Del. Apr. 20, 2005)

to Motion to Strike Impax's Unclean Hands Defense and to Dismiss Impax's Unenforceability Counterclaim ("Matterer Decl."), Ex. 1 (Letter of Feb. 21, 2006 from Wyeth to Impax) at 3. Not only were the asserted claims properly construed by the District of New Jersey as requiring microcrystalline cellulose, but the majority of the asserted claims *directly state that the patented inventions must include microcrystalline cellulose*.

Accordingly, through this lawsuit, Wyeth is attempting to extend the economic benefit of its patent beyond the patent grant. This constitutes patent misuse, which renders the patents-in-suit unenforceable under the doctrine of unclean hands.

Wyeth's motion to strike and dismiss Impax's unclean hands defense must fail because *the preceding facts are pled in Impax's Answer*. See D.I. 7 at ¶¶ 10, 58-59. Impax has, moreover, attached the District of New Jersey's *Markman* Order and Opinion to its Answer. See *id.*, Ex. A. Impax has then pled "in short and plain terms," (FED. R. CIV. P. 8(b)) that "[t]he Patents-in-Suit are unenforceable because Wyeth has unclean hands." *Id.* at ¶ 47.

Under the liberal pleading standards of Federal Rule of Civil Procedure 8, this pleading is more than sufficient to put Wyeth on notice of Impax's claim that Wyeth has rendered its patents unenforceable by using them to claim infringement by products it knows do not infringe. In deciding Wyeth's motion to strike, the Court must construe each of these facts in favor of the nonmoving party and deny the motion if the defense is insufficient under the law. *Talarowski v. Pennsylvania R.R. Co.*, 135 F.Supp. 503, 504 (D.Del.1955).

A claim of patent misuse requires a showing that the patentee alleged infringement in bad faith (for example, with knowledge that the patent was non-infringed) with an anti-competitive purpose or effect behind the allegation.

Glaverbell Societe Anonyme v. Northlak Mktg. & Supply, Inc., 45 F.3d 1550, 1558 (Fed. Cir. 1995). Impax's pleading that Wyeth brought this lawsuit with knowledge that Impax's product does not infringe in order to maintain its monopoly over the venlafaxine hydrochloride market is a sufficient basis to state a claim for patent misuse. As discovery proceeds, Impax will likely uncover additional ways in which Impax has misused its patents to anti-competitive effect. Accordingly, the Court should deny Wyeth's motion to strike this defense and to dismiss Impax's counterclaim.

Should the Court disagree with Impax and decide that Impax's pleading is defective, the proper remedy is amendment, not striking and dismissing an affirmative defense and counterclaim. The law is settled that leave to amend should be freely given. Particularly here, where Wyeth brought its motion before a case management schedule has been set, Wyeth can claim no prejudice if Impax is allowed to file an amended pleading.

III. STATEMENT OF FACTS

A. **Wyeth's campaign to maintain a monopoly over the antidepressant medication venlafaxine hydrochloride.**

Since 1993 Wyeth has sold a formulation of the antidepressant medication venlafaxine hydrochloride under the brand name EFFEXOR®. In order to extend its patent monopoly over venlafaxine hydrochloride, Wyeth filed for the patents-in-suit, which claim an "extended release formulation of venlafaxine hydrochloride." *See, e.g.*, '171 patent, Cl. 1. Through multiple continuation-in-part applications, the patents eventually issued in 2001 and 2002. Wyeth then mounted a massive marketing campaign aimed at shifting sales from EFFEXOR® to EFFEXOR® XR, the extended release formulation Wyeth claims is protected by the patents-in-suit.

Wyeth's subsequent strategy has been to attempt to enlist the courts in preserving its monopoly. First Wyeth brought suit against Teva Pharmaceuticals USA, Inc. and Teva Industries Ltd. ("Teva") on the same patents at issue here in the District of New Jersey after Teva submitted an ANDA to sell a generic version of EFFEXOR® XR. D.I. 7, Ex. A. Now Wyeth has initiated the present lawsuit.

B. The claims of the patents-in-suit require spheroids comprised of microcrystalline cellulose.

The patents-in-suit claim an "extended release formulation" of the antidepressant medication venlafaxine hydrochloride and methods for administering this extended release formulation. *See, e.g.*, '171 patent, Abstract, Cls. 1, 21.

The "extended release formulation" is a claimed element of every single claim of the patents-in-suit. It is claimed and repeatedly described in the patent specifications as having a specific list of ingredients. For example, the Abstract to the '171 patent states:

More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, *microcrystalline cellulose* and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, Abstract (emphasis added). Accordingly, while the "extended release formulation" *optionally* contains ethyl cellulose and hydroxypropylmethylcellulose, the inclusion of spheroids comprised of microcrystalline cellulose is a core component of the invention.

In fact, almost every claim of the patents-in-suit either explicitly requires microcrystalline cellulose or depends from a claim explicitly requiring

microcrystalline cellulose. For example, in the '171 patent, the first 19 out of 25 claims explicitly require microcrystalline cellulose or depend from a claim containing microcrystalline cellulose. Claim 1 is representative:

1. An extended release formulation of venlafaxine hydrochloride comprising a pharmaceutically acceptable capsule containing spheroids comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, **about 50% to about 94% microcrystalline cellulose**, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroids are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, Cl. 1 (emphasis added). Claims 2 through 18 depend from this claim and therefore also require the inclusion of microcrystalline cellulose.

There can be no disputing that Wyeth knew these claims required microcrystalline cellulose when it initiated this lawsuit.

C. The District of New Jersey construed the claims of the patents-in-suit as requiring spheroids comprised of microcrystalline cellulose.

As for the remaining claims of the patents-in-suit, these also require the inclusion of microcrystalline cellulose. This is because every claim of the patents-in-suit claim the "extended release formulation," which is specially defined by the patentee as including spheroids comprised in part of microcrystalline cellulose.

For example, in the section of the '171 specification entitled "Brief Description of the Invention," the patentee states, "[t]he formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, *microcrystalline cellulose*...." '171 patent at 2:62-3:2 (emphasis added).

Having already fully litigated the meaning of the remaining claims, Wyeth should have known that these claims, as a matter of law, require microcrystalline cellulose as well. In 2003, Wyeth sued Teva on the same patents at issue here in the United States District Court for the District of New Jersey after Teva submitted an ANDA to sell a generic version of EFFEXOR® XR. After protracted discovery in that case and a full *Markman* hearing, the District Court adopted Teva's proposed construction of "extended release formulation" and construed all of the claims of the patents-in-suit as limited to a formulation comprising venlafaxine hydrochloride and microcrystalline cellulose. *See* D.I. 7, Ex. A (Markman Opinion) at 6-13. Immediately thereafter, Wyeth settled its lawsuit against Teva and the District Court withdrew its *Markman* opinion.

The District Court based its claim construction on the intrinsic record, including the fact that the patentee acted as his own lexicographer by specially defining the claimed "extended release formulation" as including spheroids comprised of microcrystalline cellulose. *See id.*, Ex. A at 8-9; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*) ([O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee")

D. Impax informs Wyeth that the accused products *do not* contain spheroids comprised of microcrystalline cellulose.

Accordingly, to avoid infringing Wyeth's patents, Impax has not included spheroids comprised of microcrystalline cellulose in its generic extended release venlafaxine hydrochloride formulation.

Impax informed Wyeth of this fact on February 21, 2006, in its letter informing Wyeth that it had submitted an ANDA to sell its generic product. *See* Matterer Decl., Ex. 1 at 3. In fact, Impax informed Wyeth that it would not

employ a spheronization process at all in its product, as required by the claims of the patents-in-suit:

Impax's venlafaxine HCl extended release formulation does not contain microcrystalline cellulose. Our product is a capsule containing sugar spheres coated with a layer of venlafaxine hydrochloride, which is covered with a sustained-release coating. It is not prepared using a spheronization process.

Id. As a result, Impax explained, its generic product "does not literally infringe any of the claims of the '171, the '958, and the '120 patents." *Id.* at 5.

Impax further explained that its generic product would not infringe under the doctrine of equivalents, because applying the doctrine would vitiate an entire claim element – the use of spheroids comprised of microcrystalline cellulose – without substituting an equivalent element. An application of the doctrine of equivalents under these circumstances would violate the "All Elements Rule," under which "[i]nfringement may not be found under the doctrine of equivalents if a limitation is missing, that is, not replaced with an equivalent substitute." *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1568 (Fed. Cir. 1996).

E. Wyeth sues Impax knowing that Impax's product does not infringe its patents.

In the face of Impax's reassurance that it would not include the claimed microcrystalline cellulose spheroids in its product, Wyeth initiated the present lawsuit. Wyeth cannot have a good faith basis for believing that Impax will infringe its patents, given the absence of the claimed microcrystalline cellulose from Impax's formulation.

Accordingly, this lawsuit represents the latest attempt by Wyeth to discourage a much smaller generic company from competing with it in the venlafaxine hydrochloride market and to keep the cost of this anti-depressant medication at monopoly prices.

IV. ARGUMENT

A. Impax has sufficiently pled its defense and counterclaim of unclean hands.

1. The defense of unclean hands is subject to the pleading standard of FRCP 8.

The Federal Rules of Civil Procedure provide a liberal pleading standard.

As explained by the Supreme Court,

[T]he Federal Rules of Civil Procedure do not require a claimant to set out in detail the facts upon which he bases his claim. To the contrary, all the Rules require is ‘a short and plain statement of the claim’ that will give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.

Leatherman v. Tarrant County Narcotic Intelligence & Coordination Unit, 507 U.S. 163, 168 (1993) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). In fact FRCP 8 expressly provides that “[e]ach averment of a pleading shall be simple, concise, and direct.” FED. R. CIV. P. 8(e).

The Federal Rules only impose a specificity requirement “in two specific instances.” *Leatherman*, 507 U.S. at 168. Rule 9 provides that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” FED. R. CIV. P. 9(b) (cited in *Leatherman*, 507 U.S. at 168).

Wyeth attempts to argue that Impax’s unclean hands defense is subject to Rule 9(b) by saying that it is “intended to be a surrogate for alleging inequitable conduct” or is “intended to relate to other unspecified acts of fraud.” D.I. 10 at 5.

In fact, the defense of unclean hands based on patent misuse does not require an averment of fraud and is not, therefore, subject to the specificity

requirements of Rule 9(b).³ *McKesson Information Solutions*, 2005 WL 914776 at *2 (D. Del. Apr. 20, 2005) (affirming the sufficiency of a pleading of unclean hands based on patent misuse under the Rule 8 standard); *cf. France Telecom S.A. v. Novell, Inc.*, 2002 WL 31355255, *2 (D. Del. Oct. 17, 2002) (holding that a pleading of unclean hands “clearly meets the threshold sufficiency requirements of Rule 8”).⁴

Accordingly, Impax’s pleading of its unenforceability defense must be judged under the liberal pleading standard of Rule 8.

2. Impax has pled sufficient facts to support a claim of unclean hands for patent misuse.

The doctrine of patent misuse “arises from the equitable doctrine of unclean hands.” *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). Patent misuse renders a patent unenforceable when “the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.” *Id.*

³ In this regard and in other respects, patent misuse is distinct from a claim of sham litigation under the antitrust laws. “Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee’s right to exclude. Thus misuse may arise when the conditions of antitrust violations are not met.” *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998).

⁴ Wyeth cites to *France Telecom* for the peculiar proposition that six paragraphs are required to plead sufficiently unclean hands. D.I. 10 at 7. In fact, the Court in *France Telecom* did not hold that any particular number of paragraphs are required. Rather, the court found that the six paragraphs in the amended pleading at issue in that case were sufficient, but not necessarily required. 2002 WL 31355255 at *2. Moreover, *France Telecom* involved a pleading of unclean hands based on inequitable conduct. *Id.* Inequitable conduct, unlike patent misuse, does have a heightened pleading standard.

One way in which a patentee can commit patent misuse is by alleging infringement in bad faith with an anti-competitive effect or purpose behind the allegation. *Glaverbell Societe Anonyme*, 45 F.3d at 1558.

Accordingly, in order to allege unenforceability for patent misuse under the liberal pleading standard of Rule 8, Impax had to plead facts establishing that Wyeth brought this lawsuit knowing that Impax's generic product would not infringe in an attempt to maintain its anti-competitive monopoly. Impax did precisely that.

First, Impax pled that it notified Wyeth that it had filed an ANDA seeking an extended release formulation of venlafaxine hydrochloride on February 21, 2006. D.I. 7 at ¶ 10.

Impax admits that in a letter dated February 21, 2006, Impax notified Wyeth that it had filed an ANDA seeking approval to market Venlafaxine HCl Extended-Release Capsules, in 37.5, 75 and 150 mg dosage strength, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. Impax admits that Wyeth received this letter on February 22, 2006.

D.I. 7 at ¶ 10. In this letter Impax informed Wyeth that its generic formulation would not infringe the patents-in-suit either literally or under the doctrine of equivalents, because it would not contain spheroids comprised of microcrystalline cellulose. Matterer Decl., Ex. 1 at 3.

Second, Impax pled that Wyeth knew the claims of its patents require microcrystalline cellulose, because the District of New Jersey had recently construed the claims of the same three patents as requiring that ingredient. Specifically, Impax pled:

On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA to obtain approval to manufacture, use and sell an extended release venlafaxine hydrochloride dosage form, and provided certification to Wyeth

that the '171, '120 and '958 Patents would not be infringed. Wyeth sued Teva for patent infringement in United States District Court, District of New Jersey. After extensive discovery, a Markman hearing was held and that Court issued an order interpreting the claims of the '171, '120, and '958 Patents to be limited to a formulation comprising venlafaxine hydrochloride and microcrystalline cellulose. Copies of the Markman Order and Opinion are attached as Exhibit A. Thereafter, Wyeth settled the litigation with Teva but has maintained the terms of the settlement as a secret. As part of the settlement, the Markman Order was vacated.

D.I. 7 at ¶ 58.

Third, Impax pled that “Impax’s venlafaxine extended release formulation does not contain microcrystalline cellulose and does not infringe the claims of the Patents-in-Suit.” D.I. at ¶ 59.

In deciding Wyeth’s motion to strike, the Court must construe each of these facts in favor of the nonmoving party and deny the motion if the defense is sufficient under the law. *Talarowski*, 135 F.Supp. at 504. These facts are sufficient to state a claim for patent misuse because they are facts demonstrating that Wyeth brought this lawsuit in bad faith, knowing that Impax’s products would not infringe in order to maintain an anticompetitive monopoly over the venlafaxine hydrochloride market. Accordingly, Impax’s pleading is sufficient and the Court should deny Impax’s motion.

This Court found a similar pleading of patent misuse sufficient under the standards of Rule 8 in *McKesson Info. Solutions, LLC v. The Trizetto Group*. In that case, the accused infringer pled that the patent-in-suit was “unenforceable because [plaintiff] comes into Court with unclean hands. Plaintiff has committed patent misuse by attempting to enforce a patent it should reasonably know is invalid and not infringed.” *McKesson*, 2005 WL 914776, *2 (D. Del. Apr. 20, 2005). The plaintiff in that case argued that this pleading was insufficient because

the accused infringer did not allege anticompetitive effect. *Id.* This Court found the pleading sufficient, even though there is no indication that the pleading in question had the detailed factual allegations to support a patent misuse defense that are present in Impax's Answer at issue here. The Court reasoned:

In complex litigation, such as cases involving patent infringement, it is through the discovery process that the parties refine and focus their claims. At this stage in the litigation, the court declines to strike defendant's affirmative defenses until adequate discovery has been completed.

*Id.*⁵

In the present case, just as in *McKesson*, the discovery process through which the parties will refine their claims has not yet begun. Just as in *McKesson*, Impax has put Wyeth on fair notice of its unenforceability defense under the Rule 8 standard by pleading facts sufficient to support a defense of patent misuse.

Wyeth argues that Impax's pleading is nonetheless insufficient, even under the liberal pleading standard of Rule 8, because it "do[es] not allege any acts of bad faith." Wyeth Br. at 6. The bringing of a patent infringement lawsuit with knowledge that it has no merit is inherently an act of bad faith. *See Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1289 (9th Cir. 1984) ("The bad faith involved - attempting to enforce a government granted monopoly to which the patent holder knows he has no right - is as much extrinsic to the suit as it is inherent in filing a legal cause of action devoid of merit.") Contrary to Wyeth's assertion, these are "unconscionable acts having an immediate and necessary nexus to the equity that Impax seeks in this litigation." Wyeth Br. at 7 (citing

⁵ Notably, counsel who defended the sufficiency of the pleading in the *McKesson* case were the same as counsel for Wyeth here, and are now attacking the sufficiency of a far more detailed pleading. *See Matterer Decl.*, Ex. 2 at 1.

Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 398 F.Supp.2d 305, 311 (D. Del. 2005)).

In short, Wyeth is attempting to misuse the patents-in-suit to anticompetitive effect by accusing a generic product of infringement when Wyeth knows there can be no infringement. This renders Wyeth's patent unenforceable under the doctrine of unclean hands. Wyeth is on fair notice of this defense and the Court should not strike Impax's unenforceability defense and counterclaim.

B. Dismissal is an inappropriate remedy.


While Impax believes that it adequately pled unclean hands and that this Opposition Motion also adequately explains the unclean hands defense and unenforceability counterclaim to enable discovery, should the Court find otherwise, the appropriate remedy is to grant leave to amend. The Federal Rules provide that leave to amend "shall be freely given when justice so requires." FED. R. CIV. P. 15(a). "Although the trial court has discretion to grant or deny leave to amend, leave should be freely granted in accordance with Rule 15(a) unless there is an apparent or declared reason for denial." *Green v. Howard R. Young Correctional Institution*, 229 F.R.D. 99, 104 (D. Del. 2005). Absent such circumstances as "undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, and futility of amendment," leave to amend should be granted. *Id.*

In the present case, Wyeth has not alleged and cannot allege any of these extraordinary circumstances that would support denial of amendment of the pleadings. This Court should allow Impax the opportunity to explore and develop its contentions of unclean hands and unenforceability through the discovery process.

V. CONCLUSION

For the foregoing reasons, Wyeth's motion to strike Impax's unclean hands defense and to dismiss Impax's unenforceability counterclaims should be denied.

Dated: May 26, 2006


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CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of May, 2006, I electronically filed the foregoing document, **OPPOSITION OF DEFENDANT IMPAX LABORATORIES, INC. TO PLAINTIFF'S MOTION TO STRIKE IMPAX'S UNCLEAN HANDS DEFENSE AND TO DISMISS IMPAX'S UNENFORCEABILITY COUNTERCLAIM**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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Additionally, I hereby certify that on the 26th day of May, 2006, the foregoing document was served as indicated on the following:

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TAB A

Westlaw

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v.

NOVELL, INC., Defendant.

No. 102-437-GMS.

Oct. 17, 2002.

MEMORANDUM AND ORDER

SLEET, District J.

I. INTRODUCTION

*1 On May 17, 2002, the plaintiffs, France Telecom S.A. ("France Telecom"), TéléDiffusion de France S.A. ("TDF"), and U.S. Philips Corp. ("Philips") (collectively "the plaintiffs") filed this action alleging patent infringement of a computer software system for accrediting message signatures. The defendant, Novell, Inc. ("Novell"), filed its Answer and Counterclaim on July 16, 2002 (D.I.7). In its Answer, the defendant asserts ten affirmative defenses, including the affirmative defense of "unclean hands." The plaintiffs move to strike this fourth affirmative defense (D.I.8), and the defendant subsequently moved for leave to file an amended Answer (D.I.12). For the following reasons, the court will deny the plaintiffs' motion and grant the defendant's motion.

II. DISCUSSION

A. Defendant's Motion for Leave to Amend Its Answer

The defendant moves to amend its Answer pursuant to Federal Rule of Civil Procedure 15(a). Rule 15(a) provides that a party may amend its complaint "by leave of court ... and leave shall be freely given when justice so requires." FED. R. CIV. P. 15(a). Leave should be freely granted unless there is an apparent or declared reason for denial, e.g., undue delay, bad faith, or dilatory motive on the part of the movant; undue prejudice to the opposing party; or futility of the amendment. See Foman v. Davis, 371 U.S. 178, 182 (1962); see also In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir.1997). Leave to amend is par-

ticularly warranted when pleadings lack the requisite factual specificity for a particular cause of action. See District Council 47 v. Bradley, 795 F.2d 310, 316 (3d Cir.1986). Indeed, "[t]he clearest cases for leave to amend are correction of an insufficient claim or defense and amplification of previously alleged claims or defenses." U.S. v. Teeven, 1992 WL 683682, at *7 (D.Del. Oct. 27, 1992).

The plaintiffs object to Novell's motion to amend its Answer because, they argue, it is futile, as the amended Answer would remain subject to a motion to strike due to redundancy. For the reasons set out in Part B below, the court finds the two defenses are not redundant, and therefore the amendment is not futile.

Nor would the amendment prejudice the plaintiffs by complicating discovery and confusing issues at trial, as they assert. Indeed, as the plaintiffs imply in their briefs, the more particularized amended Answer will benefit the parties by providing notice of the nature and grounds of the defense and by narrowing discovery and preparation efforts.^{FNI} None of the other reasons for denial, such as undue delay, bad faith, or dilatory motive on Novell's part, has been alleged, and the court finds no evidence of such. The defendant's motion for leave to amend the Answer is, therefore, granted.

^{FNI} Referring to the defendant's unamended Answer, the plaintiffs asserted: "The unclean hands defense will prejudice plaintiffs if it remains in its present form The undefined nature of defendant's current pleading could permit defendant to change the theory of its defense, without putting plaintiffs on notice that this has occurred Defendant could also utilize the broad and undefined nature of its 'unclean hands' defense to rationalize 'fishing expeditions' on matters that would otherwise not properly be subject to discovery." Plaintiffs' Opening Brief in Support of Plaintiffs' Motion to Strike Defendant's Fourth Affirmative Defense of Unclean Hands at 7-8. These potential problems will be avoided by the amended Answer.

B. Plaintiffs' Motion to Strike Defendant's Fourth Affirmative Defense of Unclean Hands



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The plaintiffs move to strike the defendant's fourth affirmative defense of unclean hands pursuant to Federal Rule of Civil Procedure 12(f). Rule 12(f) provides that "the court may order stricken from any pleading any insufficient defense or any redundant ... matter." FED. R. CIV. P. 12(f). Motions to strike affirmative defenses are disfavored. Proctor & Gamble Co. v. Nabisco Brands, Inc., 697 F.Supp. 1360, 1362 (D.Del.1988). When ruling on such a motion, "the [c]ourt must construe all facts in favor of the nonmoving party ... and deny the motion if the defense is sufficient under the law."

*2 In its unamended form, the defendant's fourth affirmative defense reads: "The Complaint and the relief requested therein are barred, in whole or in part, by the doctrine of unclean hands." The plaintiffs contend this articulation is insufficient and redundant. They allege it is insufficient because it provides no notice of the nature of the unclean hands defense and because it does not detail the relationship between the plaintiffs' alleged inequitable conduct and the plaintiffs' claim.^{FN2} Even if amended, the plaintiffs object, the defense is redundant, because Novell also asserts the affirmative defense of inequitable conduct. The plaintiffs maintain that these two affirmative defenses share identical elements and standards of proof. If one fails, the plaintiffs contend, so must the other. The court will now address these objections in turn.

FN2. Although the plaintiffs seem to have withdrawn the insufficiency objections following the defendant's motion for leave to amend the Answer, the court will address the insufficiency objection *vis-a-vis* the amended Answer.

1. Sufficiency per Rule 8

Rule 8 of the Federal Rules of Civil Procedure requires a "short and plain" statement of a claim or defense. FED. R. CIV. P. 8(a) and (b). It is well settled that the Federal Rules intend a liberal pleading standard. See Leatherman v. Tarrant County Narcotic Intelligence & Coordination Unit, 507 U.S. 163, 168 (1993) (holding that federal courts may not impose a more demanding standard of pleading beyond "the liberal system of 'notice pleading' set up by the Federal Rules"). Indeed, Rule 8 expressly mandates that "[e]ach

averment of a pleading shall be simple, concise, and direct." FED. R. CIV. P. 8(e).

The defendant's fourth affirmative defense, as amended, comprises six short paragraphs stating the basis for the unclean hands defense, including the context of the alleged misconduct. This context includes the title, author, and publication date of the reference allegedly withheld by the plaintiffs from the Patent and Trademark Office ("PTO"). The amended affirmative defense clearly meets the threshold sufficiency requirements of Rule 8.

2. Sufficiency Per Rule 9

Rule 9 of the Federal Rules of Civil Procedure requires that all pleadings of fraud or mistake "shall be stated with particularity." FED. R. CIV. P. 9(b). Such averments, however, remain subject to the liberal pleading requirements of Rule 8. See In re Westinghouse Sec. Litig., 90 F.3d 696, 703 (3d Cir.1996); see generally 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1281, at 520-21 (1990) (pleading with particularity under Rule 9(b) should be done consistently with the general philosophy of Rule 8); 2A JAMES W. MOORE, MOORE'S FEDERAL PRACTICE P 8.13, at 8-58 (2d ed.1995) (the mandate of Rule 8 applies "even where the Rules command particularity, as in the pleading of fraud under Rule 9(b)") (footnote omitted). In the context of alleged inequitable conduct before the PTO during a patent prosecution, "pleadings that disclose the name of the [allegedly withheld] relevant prior art and disclose the acts of the alleged fraud fulfill the requirements of Rule 9(b)." EMC Corp. v. Storage Tech. Corp., 921 F.Supp. 1261, 1263 (D.Del.1996).

*3 To the extent the defendant's fourth affirmative defense involves fraud and is subject to the particularity requirement of Rule 9(b), this requirement also is satisfied by Novell's amendment. As noted above, the amended Answer discloses the title, author, and publication date of the relevant prior art allegedly withheld from the PTO. Novell's amended fourth affirmative defense suffices "to apprise the other party of what is being alleged in a manner sufficient to permit responsive pleadings" as Rule 9 requires. 5 WRIGHT & MILLER § 1296 (1990).

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3. Nexus between the Unclean Hands Defense and Plaintiffs' Claim

The defense of unclean hands requires "an immediate and necessary relation" between the plaintiff's alleged misconduct and the equity sought by that party. *See Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933) ("[Courts] apply the maxim requiring clean hands only where some unconscionable act of one coming for relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation."). Indeed, in the Third Circuit, this nexus is "the primary principle guiding application of the unclean hands doctrine." *New Valley Corp. v. Corporate Prop. Assocs.* 2 & 3, 181 F.3d 517, 525 (3d Cir.1999).

The plaintiffs object to Novell's unamended fourth affirmative defense because, they argue, it fails to disclose any relationship between the alleged inequitable conduct constituting unclean hands, and the patent infringement claim at issue. The amended fourth affirmative defense, however, makes clear this relationship. Novell alleges the defendants knowingly, and with an intent to deceive, failed to disclose relevant and material prior art to the Patent and Trademark Office. If such conduct constitutes unclean hands, it would render the patent unenforceable, and the present infringement action necessarily would fail. *See generally Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933). The relationship between the alleged inequitable conduct on the part of the plaintiffs and the equity sought by them has been made sufficiently clear by Novell's amended Answer.

4. Redundancy

The plaintiffs object to Novell's fourth affirmative defense of unclean hands as redundant because it is indistinguishable from Novell's third affirmative defense of inequitable conduct. The elements and standards of proof for the two defenses are identical, the plaintiffs contend, in the context of non-disclosure of material prior art to the PTO during the procurement of a patent.

The court is unconvinced that the two defenses are "identical," even in the context of non-disclosure to the PTO. The Federal Circuit has defined inequitable conduct as

the "failure to disclose material information, or submission of false material information, with an intent to deceive." *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 872 (Fed.Cir.1988). Unclean hands, however, remains a broader defense less amenable to a particular checklist of elements. The doctrine of unclean hands

*4 necessarily gives wide range to the equity court's use of discretion It is "not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." Accordingly one's misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character. Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim.

Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 815 (1945) (citation omitted). Although the two affirmative defenses in the instant case may well rest on the same facts and may result in identical outcomes, the defenses themselves are not necessarily identical. Particularly at this early stage in the proceedings and given the disfavor with which motions to strike affirmative defenses are received, the court will allow the fourth affirmative defense to remain, to succeed or fail as it may in the remaining litigation.

III. CONCLUSION

For the aforementioned reasons, IT IS HEREBY ORDERED that:

1. The plaintiffs' motion to strike the defendant's fourth affirmative defense of unclean hands (D.I.8) is DENIED.
2. The defendant's motion for leave to amend its Answer (D.I.12) is GRANTED.
3. The defendant shall file its amended Answer within 10 days of the date of this order.

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END OF DOCUMENT

TAB B

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HBriefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, D. Delaware.

MCKESSON INFORMATION SOLUTIONS, LLC,

Plaintiff,

v.

THE TRIZETTO GROUP, INC., Defendant.

No. Civ.04-1258-SLR.

April 20, 2005.

Thomas J. Allingham, II, Wilmington, DE, for Plaintiff.Rodger Dallery Smith, II, Wilmington, DE, for Defendant.

MEMORANDUM ORDER

ROBINSON, J.

I. INTRODUCTION

*1 On September 13, 2004, plaintiff filed this action alleging infringement of its United States Patent No. 5,253,164 ("the '164 patent") by defendant. Defendant answered the complaint, denied any infringement and asserted that the '164 patent was invalid and unenforceable. (D.I.10)

Pending before the court are plaintiff's motions to strike defendant's affirmative defenses, dismiss defendant's counter-claims or, in the alternative, for a more definitive statement of such defenses and counterclaims. (D.I.13) This court has jurisdiction over this suit pursuant to 28 U.S.C. § 1338.

II. BACKGROUND

Plaintiff is a Delaware limited liability corporation with its principal place of business in Alpharetta, Georgia. (D.I.10) Defendant is a Delaware corporation with its principal place of business in Newport Beach, California. (D.I.10) The parties create and distribute software for reviewing the accuracy of healthcare claims and/or charges. (*Id.* at ¶¶ 25-26)

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8 requires a party to set

forth affirmative defenses in a responsive pleading with a "short and plain statement." Federal Rule of Civil Procedure 12(f), in turn, states:

Upon motion by a party before responding to a pleading or, if no responsive pleading is permitted by these rules, upon motion made by a party within 20 days after the service of the pleading upon the party or upon the court's own initiative at any time, the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.

Motions to strike affirmative defenses, however, are disfavored. See Proctor & Gamble Co. v. Nabisco Brands, Inc., 697 F.Supp. 1360, 1362 (D.Del.1988). When ruling on such a motion, "the court must construe all facts in favor of the nonmoving party ... and deny the motion if the defense is sufficient under the law." *Id.* Furthermore, courts prefer not to grant a motion to strike "unless it appears to a certainty that ... [the movant] would succeed despite any state of the facts, which could be proved in support of the defense." Salcer v. Envicon Equities, Corp., 744 F.2d 935, 939 (2d Cir.1984).

IV. DISCUSSION ^{FN1}

^{FN1} Because plaintiff's motion to dismiss, or in the alternative for a more definite statement, depends solely on its motion to strike, the motion is dismissed without prejudice to renew.

Defendant's answer to the complaint asserts eight affirmative defenses and counter-claims for declaratory judgment of noninfringement, unenforceability and invalidity. (D.I.10) Plaintiff has moved to strike defendant's second, sixth and seventh affirmative defenses. (*Id.* at ¶¶ 11, 15, 16-18)

A. Second And Sixth Affirmative Defenses-Invalidity & Misuse

Defendant's second affirmative defense argues that the '164 patent is invalid "for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and 112." (*Id.* at ¶ 11) Plaintiff argues that this defense is too broad because it includes any and all of title



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35, and it is repetitive of defendant's third, fourth and fifth affirmative defenses, which asserts specific violations of §§ 102, 103 and 112. (*Id.*)

*2 Defendant's sixth affirmative defense asserts that "[t]he '164 patent is unenforceable because [plaintiff] comes into Court with unclean hands. Plaintiff has committed patent misuse by attempting to enforce a patent it should reasonably know is invalid and not infringed." (D.I. 10 at ¶ 15) Plaintiff asserts that this defense does not meet pleading requirements because it does not allege bad faith or anti-competitive effect.^{FN2}

^{FN2} The basic allegation of patent misuse is that the patentee has "extend[ed] the economic benefit beyond the scope of the patent grant." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed.Cir.1998). Patent misuse "requires that the alleged infringer show that the patentee has impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect." *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868-71 (Fed.Cir.1997). There is a two part test for patent misuse that requires the party alleging misuse to show a patentee's bad faith in alleging infringement and an anticompetitive effect or purpose behind the allegation. See e.g., *Glaverbell Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558 (Fed.Cir.1995); *Advanced Cardiovascular Systems, Inc. v. Scimed Systems, Inc.*, C-96-0950, 1996 WL 467277 at *4 (N.D.Cal.1996).

In complex litigation, such as cases involving patent infringement, it is through the discovery process that the parties refine and focus their claims. At this stage in the litigation, the court declines to strike defendant's affirmative defenses until adequate discovery has been completed.

B. Seventh Affirmative Defense-Inequitable Conduct

Defendant's seventh affirmative defense states:

The patent-in-suit is invalid and unenforceable because it was obtained through the intentional failure of the inventors, and/or their agents, to disclose to the Patent Office, during

prosecution of the patent-in-suit, information material to the patentability of the patent-in-suit, in violation of 37 C.F.R. § 1.56.

To the extent now known, and subject to further amplification as to the full extent of the withholding and misrepresentation of information, the inventors and/or their agents made a number of misrepresentations or omissions of material fact to the Patent Office, including but not limited to, false statements and omissions regarding prior art. In particular, and without limitation, the following intentional and material false statements or omissions were made by the inventors and/or their agents, including:

- a) the failure by applicants to disclose to the Examiner one of the inventors' own material prior art publications, including "An Access-oriented Negotiated Fee Schedule-The Caterpillar Experience," ... and a presentation at the 107th Annual Meeting of The American Surgical Association ...;
- b) the failure to disclose to the Examiner the fact that the claimed software to review claims was obvious and disclosed in commonly available books on expert systems as admitted by Marcia Radosevich, President of HPR, the assignee of the patent-in-suit, in a case study at the Harvard Business School in 1989;
- c) the failure to disclose to the Patent Office that four programming and code review consultants participated in the development of the claimed software as described by Marcia Radosevich to the Harvard Business School; and
- d) the failure to disclose to the Patent office that the invention was conceived by some individuals who were employed by Boston University's Health Policy Institute, and that the work was funded by the U.S. Government sponsored research.

The above false statements and omitted references and funding information would have been considered by a reasonable examiner to be material to a determination of allowability of the patent claims, and on information and belief, said statements and omissions were made with intent to deceive the Patent Office. Had the inventors and/or their agents made accurate representations to the Patent Office, the '164 patent would not have issued. Hence, the patent-in-suit is unenforceable for inequitable conduct.

*3 (D.I. 10 at ¶¶ 16-18)



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Fraud is a clear exception to the otherwise broad notice-pleading standards under Fed.R.Civ.P. 9. A claim of patent unenforceability is premised upon inequitable conduct before the Patent & Trademark Office ("PTO"), which is a claim sounding in fraud. A plaintiff alleging unenforceability, therefore, must plead with particularity those facts which support the claim the patent holder acted fraudulently before the PTO. *See e.g., Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1343-44 (Fed.Cir.2003).

This court has previously found that pleadings that "disclose the name of the relevant prior art and disclose the acts of the alleged fraud fulfill the requirements of Rule 9(b)." *See, e.g., EMC Corp. v. Storage Tech. Corp.*, 921 F.Supp. 1261, 1263 (D.Del.1996). In this case, defendant has satisfied the pleading requirements of Rule 9(b), as it states, with reasonable particularity, the prior art references and instances of fraud to which it is referring. Plaintiff is on notice of the misconduct alleged.

IV. CONCLUSION

Therefore, at Wilmington this 20th day of April, 2005;

IT IS ORDERED that:

1. Plaintiff's motion to strike certain of defendant's affirmative defenses (D.I.13) is denied without prejudice.
2. Plaintiff's motion to dismiss, or for a more definitive statement (D.I.13), is denied without prejudice.

D.Del.,2005.

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Briefs and Other Related Documents ([Back to top](#))

- [2006 WL 809129](#) (Trial Motion, Memorandum and Affidavit) McKesson's Response to Trizetto's Objections to McKesson's Means-Plus-Function Claim Construction Chart (Feb. 28, 2006)
- [2005 WL 3666827](#) (Trial Motion, Memorandum and Affidavit) The Trizetto Group, Inc.'s Motion to Enforce Com-

plaintine with the Court's September 20, 2005 Order Re: Claim Construction (Oct. 12, 2005)

• [1:04cv01258](#) (Docket) (Sep. 13, 2004)

END OF DOCUMENT